CONSENT TO PARTICIPATE IN A MEDICAL RESEARCH PROJECT

MEN'S REPRODUCTIVE HEALTH STUDY

Researchers at Kaiser Permanent Medical Centers and the California Department of Health Services are conducting a study of reproductive health. The study involves both women and their husbands. The women will be asked certain questions, requested to collect urine samples, and to keep a brief diary. The men also will be asked to respond to a questionnaire and to provide two semen samples.

The purpose of this study is to determine possible risk factors for reproductive dysfunction and undesirable outcomes of pregnancy.

It is unlikely that you will personally benefit from being in this study, other than receiving payment upon completion of the semen collection process. However, society may benefit in the future from the results of the study.

Participation in this study is completely voluntary. Therefore, your decision whether or not to be in the study, or to drop out later, will not affect the health care you receive or your eligibility for membership in Kaiser Foundation Health Plan. Although injury is most unlikely, if you are injured as a result of being in this study, as a member of Kaiser Foundation Health Plan you will be offered treatment in accordance with the member's Health Plan coverage. The researchers do not expect participants to be exposed to any risks as a consequence of involvement in this study, however.

If you agree to be in this study you will:

1. Participate in a telephone interview during which you will be asked questions about your health and reproductive history, and other factors such as occupation, smoking, and diet. The interview may take up to a half hour but will be conducted at a time convenient to you. You may refuse to answer any questions and may terminate the interview or your participation in the study at any time;

2. Provide two semen samples at a time convenient to you. These may be collected in a facility maintained by Kaiser for this study or at another location of your choice, provided that the samples are delivered immediately to this facility. One sample will be collected each month for the first two months that your wife collects urine samples for the same study, and must be collected following at least two days of not having sexual relations. These samples will be tested for sperm count and quality. They will also be tested for the presence of caffeine consumption and for metabolites (chemical breakdown products) of cigarette smoking; they will not be used for any other testing purposes. Analyses of the semen samples will be done at the following University of California laboratories: Lawrence Livermore National Laboratory, Davis, and San Francisco. At your request, the results of these tests will be provided to your physician.

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3. Provide one saliva sample. This sample will be tested for the presence of caffeine consumption and for metabolites of cigarette smoking.

For your participation in this study you will be paid $50.00 at the completion of the semen collection schedule.

All laboratory and interview data will be kept confidential and, to the extent permitted by law, will not be made available to others, including your physician, without your consent. All information from or about the study will be presented in summary form with no participants identified.

Questions, comments, or complaints, about the study may be presented to the principal investigator, Robert A. Hiatt, M.D., at (415) 987-4004 or to the Institutional Review Board for The Protection of Human Subjects, Kaiser Foundation Research Institutes, 3505 Broadway, Oakland, CA 94611, telephone (415) 987-3236.

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I have read the above and am satisfied with my understanding of the study, its possible benefits, risks, and alternatives. My questions about the study have been answered, I hereby voluntarily consent to participate in the medical research study as described. I have been offered copies of this two page consent form and of the "Experimental Subject's Bill of Rights."

Signature of Participant	Date
Names of Participant, printed	Witness (not a physician)
Robert A. Hiatt, M.D. Principal Investigator	Shanna H. Swan, Ph.D. Principal Investigator
David Rempel, M.D. Co-Principal Investigator	

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